



This is an official CDC Health Update

Distributed via Health Alert Network
December 4, 2012, 4:00 PM
10272-CHU-12-04-2012-NECC

Update: Additional Contamination Identified in Medical Products from New England Compounding Center

Summary

-As part of the ongoing investigation of the multistate outbreak of fungal meningitis and other infections, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) continue to test medical products from the New England Compounding Center (NECC) in Framingham, Mass. CDC and FDA are reporting today additional microbial contamination identified in NECC products, which updates the November 1, 2012 [Health Alert Network advisory](#). This update includes the following key points:

- CDC and FDA have identified additional [microbial contamination](#) in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC.
- These include bacteria known as *Bacillus*, and fungal species including *Aspergillus tubingensis*, *Aspergillus fumigatus*, *Cladosporium* species, and *Penicillium* species.
- Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. It is not known how product contamination with these organisms could affect patients clinically.
- To date, although CDC has received reports of illness in patients who have received the medications listed in the table below, including some patients who had evidence of meningeal inflammation, CDC and public health officials have no reports of laboratory-confirmed bacterial or fungal meningitis, spinal, or paraspinal infections caused by these products.
- The available epidemiological and laboratory data do not, at this time, support evidence of an outbreak of infections linked to usage of non-methylprednisolone NECC products.
- CDC's recommendations to healthcare providers for [diagnosing](#) and [treating](#) symptomatic patients who have received NECC products have not changed as a result of these findings.
- CDC continues to recommend that clinicians remain alert for the possibility that infections may have resulted from injection of NECC products, and that routine laboratory and microbiologic tests, including bacterial and fungal cultures, should be obtained as deemed necessary by treating clinicians.
- Clinicians should continue to report infections potentially related to NECC products to [FDA's MedWatch](#) and to state health departments.

Background

On September 26, 2012, NECC voluntarily recalled three lots of preservative-free methylprednisolone acetate (PF) 80mg/ml¹ associated with the multistate outbreak of fungal meningitis and other infections. As previously confirmed by CDC and FDA, the fungus *Exserohilum rostratum* was identified from two

different lots of NECC-supplied, preservative-free methylprednisolone acetate (Lot #06292012@26 and Lot #08102012@51); testing on the third implicated lot of preservative-free methylprednisolone acetate (Lot #05212012@68) has yet to identify fungal growth. Two types of fungus not known to be human pathogens were also identified from product from the two tested lots, namely *Rhodotorula laryngis* and *Rhizopus stolonifer*. Among these fungal organisms, only *Exserohilum rostratum* has been associated with human infections in this outbreak.

On October 6, NECC expanded its recall to include [all products in circulation](#) that were distributed from its facility in Framingham, Mass. As part of the ongoing investigation, FDA and CDC have been testing various NECC products for evidence of contamination. Laboratory testing at CDC and FDA has found bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from NECC, as shown in the table below.

Laboratory-Confirmed Organisms from Product Samples Associated with NECC Recalled Lots of Betamethasone, Cardioplegia, and Triamcinolone Solutions		
Medication	Lot Number	Bacterial and Fungal Contamination
Betamethasone 6 mg/mL injectable –5 mL per vial	08202012@141	<i>Paenibacillus pabuli/amolyticus</i> , <i>Bacillus idriensis</i> , <i>Bacillus flexus</i> , <i>Bacillus simplex</i> , <i>Lysinibacillus</i> sp., <i>Bacillus niacini</i> , <i>Kocuria rosea</i> , <i>Bacillus lentus</i>
Betamethasone 6 mg/mL injectable –5 mL per vial	07032012@22	<i>Bacillus niabensis</i> , <i>Bacillus circulans</i>
Betamethasone 12 mg/mL injectable – 5 mL per vial	07302012@52	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Paenibacillus barengoltzii/timonensis</i>
Betamethasone 6mg/mL injectable – 5 mL per vial	08202012@44	<i>Bacillus lentus</i> , <i>Bacillus firmus</i> , <i>Bacillus pumilus</i>
Betamethasone 6 mg/mL injectable – 5 mL per vial	08152012@84	<i>Penicillium</i> sp., <i>Cladosporium</i> sp.
Triamcinolone* 40mg/mL injectable – 1 mL per vial	06062012@6	<i>Bacillus lentus</i> , <i>Bacillus circulans</i>
Triamcinolone 40 mg/mL injectable – 2 mL per vial	08172012@60	<i>Aspergillus tubingensis</i> , <i>Penicillium</i> sp.
Triamcinolone 40mg/mL injectable – 10mL per vial	08242012@2	<i>Aspergillus fumigatus</i>
Cardioplegia solution 265.5 MI per bag	09242012@55	<i>Bacillus halmopalus/horikoshii</i> , <i>Brevibacillus choshinensis</i>

*Identification of other bacteria for this product is pending.

Recommendations to Healthcare Providers

FDA released a [MedWatch Safety Alert](#) on October 15 stating that the sterility of any injectable drugs, including ophthalmic drugs that are injectable or used in conjunction with eye surgery, and cardioplegic solutions produced by NECC is of significant concern. The safety alert further advised healthcare providers to follow-up with patients who were administered any of these products purchased from or distributed by NECC on or after May 21, 2012. A [sample notification letter](#) to assist with this process is available.

CDC's recommendations to healthcare providers for [diagnosing](#) and [treating](#) symptomatic patients who have received NECC products have not changed as a result of the laboratory findings reported here. CDC continues to recommend that clinicians remain vigilant for the possibility that infections may have resulted from injection of NECC products, and that routine laboratory and microbiologic tests, including bacterial and fungal cultures, should be obtained as deemed necessary by treating clinicians.

There has been no prior systematic surveillance for adverse events following epidural steroid injections; however, infection is a known, although likely rare, risk that has been documented in the medical literature. To date, although CDC is aware of reports of illness in patients who have received these medications, including some patients who had evidence of meningeal inflammation, CDC and other public health officials have no reports of laboratory-confirmed bacterial or fungal meningitis, or spinal or paraspinal infections caused by these products. The available epidemiological and laboratory data do not, at this time, support evidence of an outbreak of infections linked to usage of non-methylprednisolone NECC products.

However, because it is possible that some of the organisms listed in the table above can cause human disease, clinicians should continue to include bacterial and/or fungal infection in the differential diagnosis when evaluating symptomatic patients who were exposed to these medications, including consideration of empiric antifungal therapy.

Consultation with an infectious disease specialist is strongly encouraged to help make treatment decisions in these cases. If the evaluation of these patients is suggestive of fungal infection, please consult existing [CDC treatment guidance](#) associated with this outbreak. Physicians should continue to report infections potentially related to NECC products to [FDA's MedWatch](#) and to state health departments.

¹ NECC lots of methylprednisolone acetate (PF) 80mg/ml:

Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

DHEC contact information for reportable diseases and reporting requirements

Reporting of influenza is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2012 List of Reportable Conditions available at: <http://www.scdhec.gov/health/disease/reportables.htm>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2012

Mail or call reports to the Epidemiology Office in each Public Health Region.

Region 1

Anderson, Oconee

220 McGee Road
Anderson, SC 29625
Phone: (864) 260-4358
Fax: (864) 260-5623
Nights / Weekends: 1-866-298-4442

Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda

1736 S. Main Street
Greenwood, SC 29646
Phone: 1-888-218-5475
Fax: (864) 942-3690
Nights / Weekends: 1-800-420-1915

Region 2

Greenville, Pickens

PO Box 2507
200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 282-4139
Fax: (864) 282-4373
Nights / Weekends: (864) 809-3825

Cherokee, Spartanburg, Union

PO Box 4217
151 E. Wood Street
Spartanburg, SC 29305-4217
Phone: (864) 596-2227, x- 210
Fax: (864) 596-3443
Nights / Weekends: (864) 809-3825

Region 3

Chester, Lancaster, York

PO Box 817
1833 Pageland Highway
Lancaster, SC 29720
Phone: (803) 286-9948
Fax: (803) 286-5418
Nights / Weekends: 1-866-867-3886

Region 3 (continued)

Fairfield, Lexington, Newberry, Richland

2000 Hampton Street
Columbia, SC 29204
Phone: (803) 576-2749
Fax: (803) 576-2993
Nights / Weekends: 1-888-554-9915

Region 4

Clarendon, Kershaw, Lee, Sumter

PO Box 1628
105 North Magnolia Street
Sumter, SC 29150
Phone: (803) 773-5511
Fax: (803) 775-9941
Nights/Weekends: (803) 458-1847

Chesterfield, Darlington, Dillon,

Florence, Marlboro, Marion

145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
Fax: (843) 661-4859
Nights / Weekends: (843) 601-7051

Region 5

Bamberg, Calhoun, Orangeburg

PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 533-7199
Fax: (803) 533-7134
Nights / Weekends: (803) 516-5166

Aiken, Allendale, Barnwell

222 Beaufort Street, NE
Aiken, SC 29801
Phone: (803) 642-1618
Fax: (803) 643-8386
Nights / Weekends: (803) 645-8167

Region 6

Georgetown, Horry, Williamsburg

1931 Industrial Park Road
Conway, SC 29526-5482
Phone: (843) 915-8804
Fax: (843) 365-0085
Nights / Weekends: (843) 340-4754

Region 7

Berkeley, Charleston, Dorchester

4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 953-0047
Fax: (843) 953-0051
Nights / Weekends: (843) 219-8470

Region 8

Beaufort, Colleton, Hampton, Jasper

219 S. Lemacks Street
Walterboro, SC 29488
Phone: (843) 605-3407
Fax: (843) 549-6845
Nights / Weekends: 1-843-441-1091

DHEC Bureau of Disease Control Division of Acute Disease Epidemiology

1751 Calhoun Street
Box 101106
Columbia, SC 29211
Phone: (803) 898-0861
Fax: (803) 898-0897
Nights / Weekends: 1-888-847-0902



www.scdhec.gov

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.